Clark Regional MEDICAL CENTER

June 30, 2015

Tricia Orme
Office of Legal Services
275 E. Main St. 5 W-B
Frankfort, KY 40601

Re: 900 KAR 5:020
2015-2017 State Health Plan

Dear Ms. Orme:

I am writing on behalf of Clark Regional Medical Center ("CRMC") to comment on the proposed 2015-2017 Kentucky State Health Plan. CRMC is a LifePoint hospital located in Winchester, directly off I-64. LifePoint and Clark have long supported Kentucky's Certificate of Need program and worked with the Cabinet and its predecessors in the health planning process.

Specifically, I am writing to request that the Cabinet make a change in the review criteria for Cardiac Catheterization Services to allow for approval of programs in counties contiguous to Fayette and Jefferson. For several years, the review criteria have not allowed such approvals because of high in-migration to Lexington and Louisville hospitals. The high utilization of cardiac catheterization labs in Lexington and Louisville has precluded approval of labs in contiguous counties. This seems counterintuitive. In fact, high utilization of Lexington and Louisville catheterization services suggests that it would be appropriate to develop services in surrounding counties to make them more accessible and to off-load some of the excess from the larger hospitals.

The State Health Plan calculates utilization rates based upon the number of adult diagnostic catheterizations performed in a county per 1,000 population of that county. Thus, where there is significant in-migration to a county, by definition its use rate will be relatively high. In 2012, the most recent year for which there are published data, the adult diagnostic cardiac catheterization use rate for Fayette County under the SHP methodology was more than three times greater than the Kentucky average. This has made applications for diagnostic catheterization services in counties contiguous to Fayette unapprovable, with no relief in sight. To make matters worse, because the Pilot Programs for therapeutic catheterization services have only applied to hospitals with existing diagnostic labs, counties contiguous to Fayette (and to Jefferson) have not been allowed to participate in those projects.

This has created a very specific problem for persons travelling from eastern Kentucky via the Mountain Parkway. Tens of thousands of eastern Kentucky residents must rely on

Lexington hospitals for diagnostic catheterizations and, perhaps more significantly, for life-saving angioplasties. There is a therapeutic catheterization program in Pikeville, 142 miles east of Lexington. There is a small diagnostic catheterization program in Prestonsburg, 118 miles east of Lexington, but it does not perform angioplasty. As persons travel west along the Mountain Parkway from Prestonsburg, then south along I-64 toward Lexington, there are no catheterization programs. This is especially problematic for persons needing emergency angioplasty.

CRMC is a significant hospital located immediately off I-64 in Winchester. We are affiliated with the cardiology program at the University of Kentucky Medical Center and our hospital is staffed with UK cardiologists. A change that would allow CRMC, with the support of the University of Kentucky Medical Center, to establish diagnostic and therapeutic cardiac catheterization services would not only improve access for persons currently forced to go all the way to Lexington for these services, it would also certainly save heart muscle and lives.

We request that the Cabinet adopt a new Review Criterion 3 for applicants for comprehensive (diagnostic and therapeutic) cardiac catheterization services, a copy of which is attached hereto. This criterion would allow approval of applications for comprehensive catheterization services if the following were met: (a) The applicant is a hospital affiliated with the cardiology program of the primary teaching facility of a qualified academic medical center as defined in 900 KAR 6:130 Section 1(9); (b) The medical director and the cardiologists staffing the applicant's proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of the qualified academic medical center; (c) The applicant's hospital is located within fifty (50) road miles of the qualified academic medical center; and (d) The applicant's hospital is located in a county that does not have an existing cardiac catheterization service.

Thank you for the opportunity to submit these written comments. As always, we support Kentucky's CON program and will continue to work with the Cabinet in the health planning process.

Sincerely,

Cherie L. Sibley
Chief Executive Officer

CARDIAC CATHETERIZATION SERVICES

PROPOSED ADDITIONAL REVIEW CRITERION

3. Notwithstanding the above Criterion 1 and Criterion 2.a. and 2.b., an application to establish a comprehensive (diagnostic and therapeutic) cardiac catheterization service shall be consistent with this State Health Plan if the following criteria are met:

(a) The applicant is a hospital affiliated with the cardiology program of the primary teaching facility of a qualified academic medical center as defined in 900 KAR 6:130, Section 1(9);

(b) The medical director and the cardiologists staffing the applicant's proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of the qualified academic medical center;

(c) The applicant hospital is located within 50 highway miles of the primary teaching facility of the qualified academic medical center; and

(d) The applicant hospital is located in a county that does not have an existing cardiac catheterization service.

HMH
Harrison Memorial Hospital
a Regional Healthcare Facility

June 30, 2015

Ms. Tricia Orme
Office of Legal Services
275 East Main Street 5 W-B
Frankfort, Kentucky 40601

RE: **Proposed Changes to the State Health Plan**

Dear Ms. Orme:

Thank you for the opportunity to comment on the proposed changes to the State Health Plan. On behalf of Harrison Memorial Hospital (HMH), in Cynthiana, Kentucky, I am writing to request that the Office of Health Policy (OHP) reconsider the change in Plan standards that would both eliminate the opportunity to apply for percutaneous coronary intervention (PCI) under a pilot project and require any future applicants to have on-site open heart surgery backup. Since no application can be approved if it is not consistent with the State Health Plan, the proposed standards would effectively prohibit any new PCI programs, especially in rural areas where required travel to a facility with open heart surgery for a patient having myocardial infarction (MI) means loss of heart muscle and potential death. Especially in a state with such high incidence of heart disease and related risk factors, we believe any policy that forecloses any expansion of access to PCI is contrary to the standard of cardiac care in effect in 2015, is inconsistent with the goal of modernizing the Certificate of Need process and needlessly closes the door on the opportunity for some rural hospitals to save lives.

Background on HMH's Interest—HMH is a 61-bed acute care hospital located in Cynthiana, Kentucky. Despite its relatively small size and rural location, HMH is a sophisticated facility offering a broad range of medical and surgical specialties, including neurology, pulmonology, nephrology, gastroenterology, hematology, oncology and cardiology. HMH is the largest and most sophisticated hospital serving a broad region of north-central Kentucky, including not only Harrison County, but also the surrounding counties of Bracken, Robertson, Nicholas and Pendleton. Within its service area, there is only one other hospital, a critical access hospital (New Horizons in Owen County, which recently filed for bankruptcy). Nicholas County Hospital closed in 2014. For much of its service area, the closest facility that presently offers PCI is Meadowview Regional Medical Center in Maysville, approximately one hour away from Cynthiana.

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As a community hospital, HMH is deeply committed to meeting the healthcare needs of its rural service area, where cardiac disease, peripheral vascular disease and chronic lung disease are among the top chronic health conditions. For the past 10 years, HMH has been diligently working to develop cardiology services, with added impetus when the State Health Plan was amended to allow PCI pilot programs. In late 2011, HMH was approved for diagnostic cardiac catheterization. HMH has invested more than $2 million of capital (which is especially precious in a small rural hospital) and established a state-of-the-art

catheterization lab with a well-trained support staff, all with the goal of ultimately seeking approval to provide PCI and save lives and heart muscle. HMH's cardiology program has made particular strides since January of this year, when Dr. Matthew Shotwell, a triple board-certified, high-volume interventional cardiologist with 15 years of experience, committed to working at HMH on a full-time basis and helping HMH pursue PCI approval. Attached hereto are letters from several members of HMH's medical staff attesting to the quality of its cardiology services and the need for on-site interventional services to complete the program.

Dr. Shotwell was instrumental in developing the catheterization program at Meadowview, another small rural hospital without cardiac surgery, which was approved for PCI under a one-time opportunity in 2008. As Dr. Shotwell explained in a recent meeting with OHP officials, Meadowview has developed an extremely busy interventional program with an exceptional seven-year track record of zero mortality in elective PCIs and acute MI door-to-balloon times and outcomes which exceed national benchmarks. Meadowview's acute MI mortality is one-tenth the national average and is largely attributed to patients having such rapid access to high quality interventional cardiology care without the needless time delays in transferring to a tertiary facility. Meadowview has proven these services are safe and both meet and exceed the standard of care, as recognized by national professional colleges (ACC/AHA/SCAI). Dr. Shotwell continues to perform procedures at Maysville, even while he has committed to full-time work with HMH.

In our recent meeting with OHP officials, Dr. Shotwell provided photographic examples of arterial interventions that are already being performed in HMH's cath lab with great success. HMH is already an interventional hospital, performing urgent and emergency peripheral interventional procedures to save ischemic arms and legs while opening acutely and chronically occluded arteries, as well as opening critically blocked arteries in the kidneys and even major thoracic vessels giving rise to intracranial arteries. All of these procedures have been safely performed at HMH without cardiothoracic or vascular surgery back-up. HMH can treat basically all arterial emergencies within the body, except those producing the leading cause of death, the cardiac vessels. As these examples show, today HMH has a fully mature cardiology program that is ready, willing and able—without any additional capital investment—to begin providing high-quality PCI with experienced interventional cardiologists. The only thing HMH lacks is the state's blessing.

Perspectives on the Need to Transfer Patients—The need for HMH to be able to take the next step was starkly demonstrated by a recent patient, a 55-year old male. The patient came to the HMH emergency department (ED), was seen by Dr. Shotwell and found to be having an acute MI. All of the resources were in place for Dr. Shotwell to take the patient upstairs, perform a cath, open the coronary artery and resolve the MI. Literally within minutes, the heart attack could have been aborted and the patient would have made a full recovery and discharged home 48 hours later. Instead, the patient had to be placed in an ambulance and transported to Maysville to receive an intervention. Dr. Shotwell was helpless to do anything except follow the ambulance to Maysville in his own car. Hours later, Dr. Shotwell opened the patient's artery, but the damage was done and it was too late for a full recovery. As a result of the time lost in the transfer and transport, the patient experienced severe heart damage and now has Class 4 congestive heart failure, requiring him to wear an expensive piece of equipment called a life vest for 40 days, followed by placement of an invasive and permanent bi-ventricular pacemaker. His life is now tremendously shortened, and he will eventually require heart transplantation. Had Dr. Shotwell's hands not been tied, this patient could have recovered fully and avoided hundreds of thousands of dollars worth of surgery, but, more importantly, a shortened life forever complicated by debilitation from congestive heart failure.

It is axiomatic that, when a patient is having a heart attack, time is muscle. In calculating the available time to achieve an intervention, transport time from HMH to another facility is not the only concern. Many patients will have taken 30 or 40 minutes just getting to the first hospital. Additional time elapses in the process of determining that the patient is having an MI and needs to be transferred and making arrangements with the receiving hospital.

(HMH reviewed its last 30 consecutive emergent transfers from its ED, not limited to MIs, and found that, on average, it is 158.4 minutes from the time the patient first arrives at HMH's ED to the time of departure in an ambulance.)

While it is unquestionably helpful for patients to have diagnostic catheterization available close to home, if the diagnostic procedure indicates a need for an intervention, time and loss of heart muscle are not the only concerns with a transfer. A patient who has a diagnostic procedure followed by an intervention at another hospital experiences two punctures, which more than doubles the risk of complications from obtaining vascular access. Of course, this also means two sets of medical bills. These are just a few of the reasons that unnecessary transfers should be avoided if the resources are in place where the patient first presents.

The Proposed Changes Conflict with Current Standards of Care—The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have worked jointly since 1980 to study evidence relating to cardiac care and develop guidelines for best practices. Together with the Society for Cardiovascular Angiography and Interventions (SCAI), in 2011, they published the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (the 2011 Guidelines), a comprehensive set of guidelines on all aspects of PCI developed after review of all available data. The work product of these combined authorities is the gold standard for PCI programs in the United States.

The 2011 Guidelines conclude the following:

- Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.
- Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.
- By way of explanation, the 2011 Guidelines further state: *Primary and elective PCI can be performed at hospitals without on-site cardiac surgical backup with a high success rate, low in-hospital mortality rate and low rate for emergency CABG. The best outcomes for patients with STEMI are achieved at hospitals with 24/7 access to primary PCI. Criteria for the performance of PCI without on-site surgical backup have been proposed in an SCAI expert consensus document. Consideration of elective PCI without on-site cardiac surgical backup is thought to be appropriate only when performed by experienced operators with complication rates and outcomes equivalent or superior to national benchmarks. Accurate assessment of complication rates and patient outcomes via a regional or national data registry, so that outcomes can be compared with established benchmarks, is an important quality control component of any PCI program. Desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery. It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.*

  2011 Guidelines at 23-24

Based on the 2011 Guidelines, the proposed State Health Plan changes that would absolutely prevent any applicant from providing PCI without open heart surgery backup are, therefore, contrary to the standard of care. Rather than foreclose all options for rural hospitals to improve access to this vital, life-saving service, HMH urges the OHP to consider standards that would allow quality diagnostic programs that are consistent with the above-quoted language to make their case to a hearing officer.

Suggestions for Criteria—Based on our review of the literature, it appears that the most robust quality standards are not specific numeric measures of outcomes or other indicators, nor is there even one recognized source of benchmarking information that can be adopted as a proxy. Presumably, this is based on recognition that numeric measures of optimal outcomes will change over time and that there may be more than one registry that generates reliable benchmarking data. Rather, these expert organizations focus on quality improvement ***processes***, such as participation in a vigorous registry and other measures, to review the quality and performance of the program, but, in particular, the performance of individual operators.

The 2011 Guidelines include these recommendations to assure quality in interventional cardiology programs without coronary backup. The following is a summary of the recommendations on Page 52 of the Guidelines:

- Participation in regional and national registries, such as the NCDR CathPCI Registry, that "provide timely data that are risk-adjusted, robust, audited, and benchmarked so that clinicians, hospitals, regulatory bodies, and other stakeholders can accurately assess the quality of care delivered."
- Ongoing peer-review assessment of the clinical proficiency of each operator (with more intensive review for low-volume operators and a method to oversee perceived conflicts in peer review).
- Monitoring performance of all operators using risk-adjusted outcome models and with review of the appropriateness of procedures.
- In instances where operators are performing less than the suggested range, both institutions and operators are strongly encouraged to carefully assess whether their performance is adequate to maintain their competence" and whether they should be allowed to continue performing coronary interventions.
- The quality assessment process should include random and detailed reviews of cases with adverse outcomes to determine cause, as well as uncomplicated cases to review appropriateness and execution. "These reviews should be conducted by recognized, experienced, unbiased interventional cardiologists."
- The reviews should be timely and periodically conducted in order to provide continuous feedback to the operators.

2011 Guidelines at 23-24.[1]

We have also reviewed standards for the 28 or so states that have planning criteria for cardiac catheterization and found that the most rigorous of them are consistent in approach with 2011 Guidelines. Attached is a representative sampling, excerpts from the health planning documents of New Hampshire, Georgia, Maryland, Illinois and Tennessee.

Most of the criteria in the current State Health Plan relating to the pilot project are consistent with this approach. While we can certainly suggest a few tweaks, we think many of the existing requirements reflect the approach taken in the 2011 Guidelines. Specifically, the requirements for 24/7 availability, ACLS certification of staff, proper equipment, rigorous case selection, outcomes analysis and case review, board-certified operators, including a program director with 500 or more interventions in his/her career, and a collaboration agreement with a tertiary care hospital with open heart surgery are all consistent with the 2011 Guidelines and would promote quality care.

Thoughts on the Pilot Project—HMH takes no position on whether or not the pilot project approach to PCI applications should be continued. We understand that the OHP has had concerns about the results of the pilot

[1] See also, the ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures, summarizing recent studies and stating: "Within these studies other factors noted as contributing to the favorable outcomes in hospitals without onsite surgery included: a) submitting data to a national repository for benchmarking, b) linkage of such facilities to a tertiary care center for consultation, c) cross-training of personnel, d) similar processes and structures of care for a patient undergoing PCI, e) expeditious transfer for emergency CABG surgery and f) use of risk-adjustment tools for case selection, outcomes analyses and comparison of operator performance. The 2013 Update goes on to emphasize the 2011 Guidelines' focus on quality assurance processes, and the importance of having operators with sufficient volumes of interventional cases.

project, both in terms of the administrative cost of monitoring the facilities in the pilot and an apparent belief that the quality has not been satisfactory.[2] However, regardless of the accuracy of any such impression, forever banning any facility from performing PCI without open heart surgery is to "throw the baby out with the bath water." It would be far better for the residents of rural Kentucky to have standards that are adjusted to address the OHP's concerns.

As noted above, whether or not the standards are part of a "pilot project" or a more routine certificate of need application, we believe many of the standards that are in the current Plan provisions for pilot projects are appropriate and would advance the goals of quality. We agree that the post-pilot evaluation standard in the current Plan, which blesses programs whose success rates are is within two standard deviations of national averages, is not rigorous enough. If there is to be a pilot project, the requirement should be for the facility to equal or exceed national benchmarks.

If OHP prefers to avoid the administrative cost of overseeing the results of the pilot project, that sort of oversight could be accomplished another way. One possibility would be to have the facility performing PCI without open heart backup include in its collaboration agreement with a tertiary care facility requirements relating to the tertiary care center's involvement in peer review, quality assessment and review of the facility's performance in comparison to national benchmarks. If the collaborating tertiary care facility recognizes quality issues in the PCI program, it can terminate its collaboration agreement or require the PCI program to implement a plan of correction. In other words, oversight by the collaborating tertiary care facility would serve as a proxy for administrative review by the OHP.

As a final plea, we urge the OHP to respect the significant investment of time and precious resources that facilities like HMH have made in the development of their cardiac catheterization programs. Abrupt discontinuance of the opportunity to pursue PCI, precisely at the time HMH's program is maturing to the point that it can present a quality proposal for PCI, essentially "pulls the rug out from under its feet." HMH (and there may be one or two other facilities that are similarly situated) deserves the opportunity to make its case to a hearing officer. More importantly, it deserves the opportunity to finish what it started for the benefit of the rural communities it serves. Accordingly, we would suggest that the opportunity to apply for PCI (under a pilot program or otherwise) should be accorded to "an acute care hospital that provides diagnostic catheterization and can demonstrate that, as of July 1, 2015, it has invested the necessary capital and otherwise made material progress toward the initiation of interventional cardiology services."

Thank you for your consideration of our comments.

Sincerely,

Sheila M. Currans

Sheila M. Currans
Chief Executive Officer

SMC:cmh
attachments

61362802.1
Cardiac Cath-Proposed Changes-Orme 150630

[2] We note that, despite our inquiry, we are not aware of any systematic evaluation of the outcomes or other quality indicators of the pilot that has been done by the OHP, and would caution against drawing conclusions from a few bad outcomes without appropriate understanding of the clinical circumstances.

Licking Valley
Internal Medicine & Pediatrics, P.S.C.

Stephen A. Besson, M.D.
Andrew R. Usery, M.D.

WM. Frank McKemie, Jr. MD, Emeritus

Lauren D. Blackwell, DO
Sarah Lindsay Florence, APRN

June 22, 2015

To Whom It May Concern:

Re: Harrison Memorial Hospital - Cardiovascular Certificate of Need

Over the past several months, the citizens of Harrison, Nicholas, and Robertson counties have had the benefit of increased cardiovascular services at Harrison Memorial Hospital, including diagnostic heart and peripheral vascular catheterization services.

Under the direction of Dr. Matthew Shotwell, our expanded service lines have helped our patients enjoy a better quality of life, and directly impacted our ability to help patients with critical diseases, such as myocardial infarctions, acute coronary syndromes, and severe peripheral arterial disease.

I can attest that scores of my patients have been able to enjoy the benefit of locally available state-of-the-art cardiac care.

I can also tell you that I have had several patients whose lives have literally been saved by our ability to intervene in their care in this community.

I, along with the rest of the medical staff at Harrison Memorial Hospital would strongly wish that we could expand our service lines even further to provide interventional cardiac catheterization services and further impact the health and mortality of our community in a positive way.

Thank you in advance for your attention in this matter.

Sincerely,

Stephen A. Besson, MD

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HMH Physician Group

Michael S. Gainey, MD, Primary Care
Tel (859)234.4494 • Fax (859)234.4498

F. Daniel Mongiardo, MD, ENT
Tel (859)235.3600 • Fax (859)234.3967

James Pettey, MD, Orthopaedics
Tel (859)234.1707 • Fax (859)234.1768

22 June 2015

To: Whom It May Concern

RE: Interventional Cardiac Catherization Lab

From: James Pettey, M.D.

Please allow me to lend my support toward authorization of the request by Harrison Memorial Hospital (HMH) in Cynthiana Kentucky to provide interventional cardiology services.

As you may be aware, HMH offers a state of the art cardiac catheterization facility capable of advanced interventional procedures such as stent placement. We have the distinct privilege of having a skilled and experienced interventional cardiologist, Dr. Matthew Shotwell, on our staff.

It is my honor to be serving as the chief of the medical staff here at Harrison Memorial Hospital, and it is my opinion that our entire medical staff is in agreement that providing interventional cardiology services here would greatly enhance the welfare of patients not only in Harrison County but also in surrounding counties with limited access to healthcare and dependent on HMH for definitive cardiology services.

As Dr. Shotwell can explain far better than I, in ischemic myocardial disease, minutes equal muscle. Many of our acute cardiac patients simply cannot tolerate the additional time that transportation to Lexington entails and as a result, would incur additional irreversible myocardial damage. This tragedy would be totally preventable by timely, safe, and appropriate cardiac intervention allowing rapid reestablishment of myocardial blood flow which can be easily provided here at Harrison Memorial Hospital.

As a retired USAF orthopaedic surgeon, I can attest that all branches of the military now subscribe to the doctrine of providing near immediate initial surgery for battle injured military members. We now place mobile surgical facilities within minutes of a battle zone. It has been proven that rapid control of hemorrhage and reestablishment of blood flow as soon as possible results in far more viable skeletal muscle and organs, and vastly increases survival rates. It is the same with myocardial tissue.

HMH Physician Group

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James Pettey, MD, Orthopaedics
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I strongly urge you to grant approval of the request for Harrison Memorial Hospital to provide interventional cardiac services. This action will have an extremely positive effect on the outcome of our patients and greatly enhance the healthcare of the citizens of our great Commonwealth.

Sincerely,

James Pettey, M.D.
Col. (retired), USAF, MC,FS

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Tel: 859.235.3638

To Whom It May Concern:

I am M.S. Gainey MD in Cynthiana Ky. I have been affiliated with Harrison Memorial Hosptial for over 20 years.

This letter is in reference to our local independent hospital, Harrison Memorial Hospital. Cynthiana, Ky. Dr. Matt Shotwell, interventional Cardiologist, has been on staff since January 2015. Since his arrival at Harrison Memorial as a full time Cardiologist, patient care has improved significantly with the patients who have had complaints of chest pain, having hypertension and or peripheral vascular disease. Currently Dr. Shotwell has done intervention of peripheral vessels as well as renals to increase circulation of bilateral lower extremities and decrease blood pressure . Dr. Shotwell has been able to perform diagnostic heart catheterizations on local residents that have entered our doors and prevented them unnecessary travel unless intervention is or was needed. With high rates of diabetes mellitus, tobacco abuse and high cholesterol in our area, this has been a terrific service to offer our patients. With Dr. Shotwell on staff and using him at his full potential as a interventional Cardiologist we can improve patient care and potential outcomes for our community.

Sincerely,

MS Gainey MD

A. C. Wright, M.D., P. S. C.
A. C. Wright, M.D.
Stephen A. Moses, M.D.
430 E. Pleasant St. ~ Cynthiana, KY 41031
Phone: 859-234-3282 ~ Fax: 859-234-9400

June 23, 2015

RE: Certificate of Need

To Whom It May Concern:

I am a full time family medicine physician in Cynthiana, KY and am affiliated with Harrison Memorial Hospital. On a daily basis I see patients with high blood pressure, diabetes, and high cholesterol; these are just a few of the risk factors for heart disease. Since January 2015 our hospital has benefitted from the full time presence of Dr. Matthew Shotwell who is providing cardiology services. During this time Dr. Shotwell has performed diagnostic catheterizations that have allowed for timely diagnoses and decision making in helping not just my patients but the patients of my fellow physicians. While the cardiac catheterization lab at Harrison Memorial Hospital has existed for several years it has largely gone underutilized until Dr. Shotwell arrived.

Now your help is needed. By granting a certificate of need for use of our cardiac catheterization lab for more than just diagnostic procedures the residents of Cynthiana and surrounding communities will benefit. Not only will our patients benefit from the interventions Dr. Shotwell can provide, they will benefit from the timely access to records that this will provide for physicians. They will also benefit from the ability to stay closer to home. I myself have had multiple patients who have had to wait nearly 72 hours for transfer to an outside hospital after having a heart attack; those were the days prior to Dr. Shotwell. Granting a certificate of need for cardiac interventions will allow all of us to take better care of our patients.

Sincerely,

Stephen A. Moses, M.D.
SAM/rs

CARDIAC CATHETERIZATION STANDARDS IN OTHER STATES

New Hampshire Standards for Adult Cardiac Catheterization Laboratory Services, Ch. He-Hea 1102.02, "Quality Assurance Requirements"

(a) Any applicant for adult cardiac catheterization laboratory services shall demonstrate the availability of a **quality assurance plan** to objectively and systematically monitor patient care.

(b) Demonstration of a quality assurance plan shall be made by submitting with the application a copy of an existing or proposed plan specific to the adult cardiac catheterization laboratory services begin offered which is consistent with the hospital-wide quality assurance plan.

(c) The quality assurance plan shall

1. Contain patient selection criteria by procedures;
2. Contain formal transfer agreements per He-Hea 1102.01(c)(2), and emergency protocols for transfer to another facility which:
    a. Specify the protocol for transfer to another facility; and
    b. Include the following:
        i. Signature of both hospitals; and
        ii. Dated with the past 12 months of submission with the application;
3. Describe the mentoring program for licensed physicians, which shall include operator volume requirements; and
4. Describe the process of cross-facility case review and outcomes analysis with the receiving facility for patients that have been transferred. "

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Georgia – State Health Plan and CON Rules for Adult Cardiac Catheterization 111-2-2-.21

"(1) An application for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordinator of service, as evidenced by regular and ongoing planning and **quality improvement** sessions with community health providers and advocacy programs;
2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the application or DTRC [diagnostic, treatment, or rehabilitation center] as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professional practicing in facilities and programs other than the applicant hospital or DTRC;...."

*****

Maryland State Health Plan for Facilities and Services: PCI Services, pp. 46-48

D. Primary PCI Services

(5) Quality

(a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients

(b) The hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period.

(d) The hospital shall evaluate the performance of each interventionalist through an annual review of:

i. At least 10 cases or 10 percent of randomly selected PCI cases performed by the interventionalist, whichever is greater; or

ii. If fewer than 10 cases have been performed, then all cases shall be reviewed.

(e) The performance review shall:

i. Include a review of angiographic images, medical test results, and patients' medical records; and

ii. Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

(f) Hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review of cases.

i. The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

ii. All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

iii. Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

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Illinois Health Care Facilities Plan Section 1110.1330 Cardiac Catheterization Review Criteria

a) "Peer Review" – Review Criteria

Any applicant proposing the establishment or modernization of a cardiac catheterization unit shall detail in its application for permit the mechanism for adequate peer review of the program. Peer review teams will **evaluate the quality** of studies and related morbidity and mortality of patients and also the technical aspects of providing services such as film processing, equipment maintenance, etc.

*****

Tennessee SHP CON Standards and Criteria for Cardiac Catheterization Services, p. 13

4. **Quality Control** and Monitoring: Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to , program outcomes and efficiency. In addition, the application should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.

At p. 20

4. **Quality Control** and Monitoring: The Division had considered requiring applicants to participate in the NCDR. Respondents to the Questionnaire agreed with the intent of such a requirement, however most indicated that the costs of participation in NCDR is burdensome, especially for new cardiac cath programs. Consequently, this standard seeks to ensure that applicants will develop a comprehensive quality control system that best fits their circumstances and that applicants participate in ongoing efforts to improve the overall quality of cardiac care in TN.

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HIGHLANDS REGIONAL
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June 30, 2015

Tricia Orme
Office of Legal Services
275 East Main Street 5 W-B
Frankfort, KY 40601

RE: Proposed Changes to the State Health Plan

Dear Ms. Orme:

Highlands Regional Medical Center (HRMC) appreciates the opportunity to comment on the proposed changes to the State Health Plan (SHP). HRMC supports the Cabinet's efforts to modernize the Certificate of Need (CON) program. However, HRMC urges the Cabinet to reconsider the proposed changes that would eliminate the opportunity to establish a percutaneous coronary intervention (PCI) as a pilot project and require applicants to have on-site open heart surgery back-up. The proposed changes to the cardiac catheterization criteria are not in sync with the national standard of care for cardiac patients and the Cabinet's goals as enumerated in its Special Memorandum regarding CON modernization. Further, the proposed changes would serve to limit access to PCI programs for patients residing in rural areas. In rural areas, travelling to a facility with open heart surgery is often unrealistic and maybe fatal for a patient experiencing myocardial infarction. For a state with a high incidence of heart disease and related risk factors, these proposed changes simply would not serve the best interests of Kentuckians.

HRMC has operated a cardiac catheterization program since 1986. Recently, HRMC has worked to be able to expand its diagnostic cardiac catheterization program to include therapeutic cardiac catheterization. In this vein, HRMC has contracted with CardioSolution, which has a proven track record of developing PCI programs which meet and even exceed the criteria set forth by the Society of Coronary Intervention and Angiography, American College of Cardiology and American Heart Association (the "Cardiology Societies") and with risk adjusted outcomes comparable to any program across the country. All of the physicians are board certified and have extensive experience as independent operators and a history of successfully performing PCI without on-site backup.

There is extensive research available that demonstrates that PCI without on-site backup can be performed safely and that it benefits rural communities. In 2011, the Cardiology Societies published the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (the "2011 Guidelines"), a comprehensive set of guidelines for PCI programs in the United States. According to the 2011 Guidelines, "Primary and elective PCI can be performed at hospitals without on-site cardiac surgical backup with a high success rate, low in-hospital mortality rate, and low rate for emergency CABG." Additionally, in 2012, the American College of Cardiology stated that "the remarkably low risk now associated with diagnostic cardiac catheterization suggests that only a few cardiovascular patients cannot safely undergo procedures in laboratories [without on-site surgical backup]." Further, as set forth in their "Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site

Surgical Backup" (the "2014 Consensus"), the Cardiology Societies have stated that where transport to a hospital with on-site surgical backup is less than thirty minutes, then it is safe to transport the patient to the nearest Percutaneous Coronary Intervention (PCI) center. However, in areas where transport to the nearest hospital with on-site surgical backup is greater than thirty minutes, it is safer for the patient if the facility performs PCI on-site (see **Attachment A**). Further, several studies have examined both primary and elective PCI without on-site surgical back-up and found no difference for in-hospital mortality or 30-day mortality between sites with and without surgical back-up. Based on the data and understanding that this life-saving therapy can now be delivered safely to rural communities, a majority of states have embraced both primary and elective PCI and allow adequately prepared hospitals to perform these procedures.

In our own community, it is apparent that additional PCI services are needed. From January 2014 to January 2015, HRMC completed 435 diagnostic angiograms with a complication rate <0.5%, which is consistent with national norms. Of the 435 diagnostic procedures, 320 (73%) had disease requiring further intervention – far above the national average, suggesting that there is a tremendous burden of coronary artery disease in this patient population. Sixty-three patients were transferred to another facility via ambulance at a cost of almost $2,000,000 (4645 miles at $395 per mile), and this cost estimate does not include costs borne by the patients and their families. This is a substantial economic burden to both the patient and the insurer.

The 2011 Guidelines, the 2014 Consensus, and extensive national and local data confirm that the proposed SHP changes, which would prohibit any applicant from providing PCI without open heart surgery backup, are not consistent with national standards of care nor do they serve the safety and health of Kentucky residents. HRMC urges the Cabinet to allow quality diagnostic programs that are consistent with the above-quoted language to apply for permanent therapeutic programs. HRMC recommends that standards for such applications be based on the 2011 Guidelines:

1. Participation in regional and national registries, such as the NCDR CathPCI Registry, that "provide timely data that are risk-adjusted, robust, audited, and benchmarked so that clinicians, hospitals, regulatory bodies, and other stakeholders can accurately assess the quality of care delivered."

2. Ongoing, peer review assessment of the clinical proficiency of each operator (with more intensive review for low-volume operators and a method to oversee perceived conflicts in peer review)

3. Monitoring performance of all operators using risk-adjusted outcome models and with review of the appropriateness of procedures

4. "In instances where operators are performing less than the suggested range, both institutions and operators are strongly encouraged to carefully assess whether their performance is adequate to maintain their competence" and whether they should be allowed to continue performing coronary interventions.

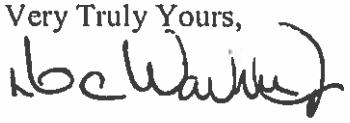
5. The quality assessment process should include random and detailed reviews of cases with adverse outcomes to determine cause, as well as uncomplicated cases to review appropriateness and execution. "These reviews should be conducted by recognized, experienced, unbiased interventional cardiologists."

6. The reviews should be timely and periodically conducted in order to provide continuous feedback to the operators.

2011 Guidelines at 23-24.[1] While existing Kentucky regulations (900 KAR 6:120) set forth reporting and quality assurance requirements that are largely consistent with the 2011 Guidelines, HRMC understands the Cabinet's concern with the current low threshold for allowing a pilot program to transition from "pilot" status to "permanent." As such, HRMC is eager to provide the Cabinet with recommended standards transitioning pilot programs to permanent status. HRMC is currently developing such standards and will provide these to the Cabinet within the next week.

Thank you for your time and consideration. Please do not hesitate to contact me if you wish to discuss our recommendations further.

Very Truly Yours,



Harold C. Warman, Jr.

[1] See also, the ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures, summarizing recent studies and stating: "Within these studies other factors noted as contributing to the favorable outcomes in hospitals without onsite surgery included: a) submitting data to a national repository for benchmarking, b) linkage of such facilities to a tertiary care center for consultation, c) cross-training of personnel, d) similar processes and structures of care for a patient undergoing PCI, e) expeditious transfer for emergency CABG surgery and f) use of risk-adjustment tools for case selection, outcomes analyses and comparison of operator performance. The 2013 Update goes on to emphasize the 2011 Guidelines' focus on quality assurance processes, and the importance of having operators with sufficient volumes of interventional cases.

only 79.9%, with the median driving time reduced by <1 min to 10.5 min.[47] Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population.[48] Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access.[49] In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment.[50,51] The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain. This can be an additional financial motivator for developing PCI facilities.[52] How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely.[53,54] However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transferring patients to tertiary hospitals.

The Volume-Outcome Relationship for PCI and the Certificate of Need

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined.[55] Despite this, they found no evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality.[56,57] Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service.[52,58] Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy.[59–63] Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective.[64] Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study.[65] In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI.[4] The document concluded that in the current era, volume outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be consistently associated with worse outcomes. Primary PCI volume ≤ the guideline-recommended minimum of 36 annually was associated with worse in hospital mortality in a recent series of over 86,000 patients in the NCDR.[66] The cutoff points of <200 total PCIs annually and ≤36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤200 total PCIs annually and 38% performed ≤36 primary PCIs annually.[8,66] Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies.[4] Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

Recommendations

We have provided recommendations for PCI without on-site surgery that are a composite of recommendations from the 2007 SCAI Expert Consensus Statement, the 2011 PCI guidelines, the 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the 2013 PCI Competency statement and recommendations from the policy statement of the American Heart Association and requirements for the Mission Lifeline program and D2B Alliance.[1–4,40,43,44] Redundant recommendations from these documents were consolidated, and the writing committee included several new recommendations consistent with evolving practice standards.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document[4] (Table 3).

Table 3. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery.* Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.*	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.* Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table 5).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL
STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including: • Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes. • A process for prehospital identification and activation. • Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI Receiving Center. • A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers. • Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	2009 PCI-GL 2011 PCI-GL ML D2B
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML

(*Continued*)

Table 3. Continued

General Recommendations	Source
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis: a. Door-to-first device time, nontransfer patients b. STEMI Referral Hospital ED door-to-balloon [first device used] time c. First medical contact to balloon inflation [first device used] time, nontransfer patients d. First medical contact to balloon inflation [first device used] time, transfer patients e. Proportion of eligible patients receiving reperfusion therapy f. Proportion of eligible patients administered guideline-based class I therapies g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who I. do not undergo acute catheterization because of misdiagnosis II. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h h. In-hospital mortality	ML

*Required for U.S. facilities but might not be possible for all facilities worldwide.

ACC, American College of Cardiology; AHA, American Heart Association policy statement; CT, computed tomography; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; EMS, emergency medical systems; GL, Guidelines; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; ML, Mission Lifeline; MR, magnetic resonance; New, New recommendation in this document; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-segment elevation myocardial infarction.

Italics font: New or modified recommendation in the document.

Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued

Table 4. Personnel Requirements for PCI Programs Without On-Site Surgery

Personnel Recommendations	Source
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	PCI GL PCI-CS
Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, *management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.*	PCI-GL PCI-CS *New*
Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	PCI-GL
Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.	PCI CS,
Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year [averaged over a 2-year period] to maintain competency.	PCI-CS
Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.	PCI-CS ML
Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.	PCI-CS
It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.	*New*

ABIM, American Board of Internal Medicine; ML, Mission Lifeline; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; IABP, intra-aortic balloon pump; New, new recommendation in this document; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Italics font: New or modified recommendation in the document.

Table 5. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations–Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.*	PCI-GL ECD *New*
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. *Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.*	PCI-GL ECD *New*
Recommendations - Case Selection and Management	
Avoid intervention in patients with: • >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired. • Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography. • Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms). • Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI. • Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention. • *Chronic total occlusion.* *The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.*	PCI-GL ECD *New*
Emergency transfer for coronary bypass surgery patients with • High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support. • Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.	PCI-GL ECD

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

Italics font: New or modified recommendation in the document.

operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access.[46–49] If the transfer time is ≤30 min, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been

Table 6. Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

High-risk patients	Source
• Decompensated congestive heart failure [Killip Class ≥3] without evidence for active ischemia.	PCI-GL
• Recent [<8 weeks] cerebrovascular accident.	AHA
• Advanced malignancy.	ECD
• Known clotting disorders.	
• LVEF ≤30%.	
• Chronic kidney disease [creatinine >2.0 mg/dL or creatinine clearance <60 mL/min].	
• Serious ongoing ventricular arrhythmias.	
• Patients with left main stenosis [>50% diameter] or three-vessel disease unprotected by prior bypass surgery [>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries], treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure.	
• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.	
• Patients undergoing intervention on the last remaining conduit to the heart.	
High-risk lesions	
• Unprotected left main stenosis.	PCI-GL
• Diffuse disease [>20 mm in length].	ECD
• Extremely angulated segment [>90%] or excessive proximal or in-lesion tortuosity.	*New*
• More than moderate calcification of a stenosis or proximal segment	
• Inability to protect major side branches.	
• Degenerated older vein grafts with friable lesions.	
• Substantial thrombus in the vessel or at the lesion site.	
• Any other feature that could, in the operator's judgment, impede successful stent deployment.	
• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.	
The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.	*New*
Strategy for surgical backup based on lesion and patient risk	
• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.	PCI-GL
• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.	
• Non-high-risk patients with high-risk lesions require no additional precautions.	
• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.	

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

Italics font: New or modified recommendation in the document.

consistently addressed in prior documents. Both CPORT-E and MASS-COMM studies provide guidance contained in their on-line supplementary materials.[9,11] Both require a transport vehicle to be available to begin transport within 30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. MASS COMM further recommends that surgical intervention begin within 120 min. Given the existing data on the distribution of PCI facilities in the US, the performance of elective PCI at facilities that cannot meet these transfer times is discouraged.[46,47]

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistical certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized.[67,68] Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence [ACE] are recommended as resources for improving quality.[69,70]